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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/258,553 02/26/99 WEAVER

E P03592US1

EXAMINER

HM12/0405

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FWO/NT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

04/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/258,553**

Applicant(s)

**Weaver, E.**

Examiner

**G. R. Ewoldt**

Group Art Unit

**1644**



☒ Responsive to communication(s) filed on Jan 16, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 10-17 and 21-24 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 10-17 and 21-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

#### DETAILED ACTION

1. Claims 10-17 and 21-24 are pending and being acted upon.
2. In view of Applicant's Amendment and Remarks, filed 1/16/01, all previous rejections have been withdrawn.
3. The following are New Grounds for Rejection necessitated by Applicant's amendment, filed 01/16/01.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  
A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
5. Claims 10-12, 14-17, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,512,282 (1996, IDS).

The '282 patent teaches a method of internally administering a composition to an animal which comprises polyclonal, monospecific, verotoxin-specific antibodies isolated from animal (bovine) serum. The reference further teaches that the dried serum is administered to a mammal orally as a powder through its feed, said feed comprising a dairy product (see particularly column 9, line 59 - column 11, line 36). Note that the claims recite a method comprising administering "antibodies to verotoxin-producing organisms and their toxins." Therefore, the method of reduction of the number of verotoxin-producing organisms is an inherent property of the method taught by the prior art.

The reference anticipates the claimed invention.

6. Claims 10-12, 14-17, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,096,244 (1978).

The '244 patent teaches a method of internally administering a composition to an animal which comprises polyclonal, monospecific antibodies isolated from animal serum. The reference further teaches that the serum is bovine or porcine and that the dried, powdered serum is administered to a mammal orally as a powder through its feed, said feed comprising a dairy product (see particularly Example 1). Note that the claims

recite "reducing the number of verotoxin-producing organisms in the colon of animals" by administering a serum composition. The specification discloses that the antibodies enabling said reduction are inherent to the serum. Therefore, the method of reduction of the number of verotoxin-producing organisms is an inherent property of the method taught by the prior art. The instant specification merely comprises further characterization of the method of the prior art; said further characterization lends no patentable weight to the claimed invention.

7. Claims 10-12, 14-17, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,623,541 (1986).

The '541 patent teaches a method of internally administering a composition to an animal which comprises polyclonal, monospecific antibodies isolated from animal serum. The reference further teaches that the serum is bovine or porcine and that the dried, powdered serum is administered to a mammal orally as a powder through its feed, said feed comprising a dairy product (see particularly Figures 1-3 and column 6, BIOLOGICAL (ANIMAL) TEST). See, Note regarding "reducing the number of verotoxin-producing organisms in the colon of animals" by administering a serum composition, supra.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 13, 21, and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,096,244 (1978) or U.S. Patent No. 4,623,541 (1986).

The '244 and '541 patents have been discussed, supra. The references differ from the claimed invention in that they do not teach the administration of the serum composition in a dose of about 1-30 g per day nor the administration of the composition comprising a neutralization titer of greater than 1:8. However, the optimization of dosages and titers are obvious and routine in the art. Said optimization, therefore, would fall well within the purview of one of skill in the art.

10. No claim is allowed.


11. Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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April 4, 2000

  
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